UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,504	10/18/2000	Frederic DeSauvage	P1748R1	6723

7590 12/11/2001

Genentech Inc
Atulya R Agarwal Ph D
1 DNA Way
South San Francisco, CA 94080-4990

EXAMINER
ROARK, JESSICA H

ART UNIT	PAPER NUMBER
1644	6

DATE MAILED: 12/11/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/692,504	Applicant(s) DESAUVAGE ET AL.	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Sequence Compliance

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. The following is noted:

Independent Claims 1 and 3 broadly recite "antagonists" and independent claims 15 and 17 broadly recite "agonists" that are utilized in the instant methods. Dependent claims 6-11 and 14 recite specific classes of "antagonists" that do not share *a substantial structural feature essential to a common utility*. Dependent claims 21-23 and 26 recite specific classes of "agonists" that do not share *a substantial structural feature essential to a common utility*. Individual antagonists and agonists that to not share *a substantial structural feature essential to a common utility* are subject to restriction, rather than election of species (as per MPEP 803.02), within the context of the particular method.

The restriction has therefore been set forth for the methods encompassing each recited structurally distinct antagonist and each recited structurally distinct agonist as separate groups, irrespective of the format of the claims.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5 (in part) and 6, drawn to a method of enhancing differentiation of T cells into a Th2 subtype or treating a Th1-mediated disease by administering/contacting with a TCCR antagonist that is a **small molecule**, classified in Class 514, subclass 1.

II. Claims 1-5 (in part), 7 (in part) and 8, drawn to a method of enhancing differentiation of T cells into a Th2 subtype or treating a Th1-mediated disease by administering/contacting with a TCCR antagonist that is an ***RNA* antisense oligonucleotide**, classified in Class 514, subclass 44.

III. Claims 1-5 (in part), 7 (in part) and 9, drawn to a method of enhancing differentiation of T cells into a Th2 subtype or treating a Th1-mediated disease by administering/contacting with a TCCR antagonist that is an ***DNA*** **antisense oligonucleotide**, classified in Class 514, subclass 44.

IV. Claims 1-5 (in part) and 10, drawn to a method of enhancing differentiation of T cells into a Th2 subtype or treating a Th1-mediated disease by administering/contacting with a TCCR antagonist that is a **TCCR variant lacking biological activity**, classified in Class 424, subclass 184.1.

V. Claims 1-5 (in part) and 11-13, drawn to a method of enhancing differentiation of T cells into a Th2 subtype or treating a Th1-mediated disease by administering/contacting with a TCCR antagonist that is an **antibody or antibody fragment**, classified in Class 424, subclass 130.1.

VI. Claims 1-5 (in part) and 14, drawn to a method of enhancing differentiation of T cells into a Th2 subtype or treating a Th1-mediated disease by administering/contacting with a TCCR antagonist that is a **TCCR ligand**, classified in Class 424, subclass unknown, possibly 85.1.

VII. Claims 15-20 (in part) and 21, drawn to a method of inhibiting differentiation of T cells into a Th2 subtype or treating a Th1-mediated disease by administering/contacting with a TCCR agonist that is a **small molecule**, classified in Class 514, subclass 1.

VIII. Claims 15-20 (in part), 22 and 26, drawn to a method of inhibiting differentiation of T cells into a Th2 subtype or treating a Th1-mediated disease by administering/contacting with a TCCR agonist that is a **TCCR polypeptide or variant thereof (including TCCR ECD) having biological activity**, classified in Class 424, subclass 184.1.

X. Claims 15-20 (in part) and 23-25, drawn to a method of inhibiting differentiation of T cells into a Th2 subtype or treating a Th1-mediated disease by administering/contacting with a TCCR agonist that is an **antibody or antibody fragment**, classified in Class 424, subclass 130.1.

XI. Claim 27, drawn to a method for determining the presence of a TCCR polypeptide in a cell using an anti-TCCR antibody, classified in Class 435, subclass 7.1.

XII. Claim 28, drawn to a method for diagnosing by detecting the level of a gene encoding a TCCR polypeptide, classified in Class 435, subclass 6.

XIII. Claims 29-34, drawn to a method for identifying a compound capable of inhibiting expression or the biological activity of a TCCR polypeptide, classified in Class 435, subclass 7.8.

5. Groups I-XIII are different methods. Each method differs with respect to one or more of ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

9. This application contains claims directed to the following patentably distinct species of the claimed Invention I: wherein the Th1-mediated disease is:

A) an autoimmune inflammatory disease, or

B) allograft rejection.

If Applicant elects Species A, Applicant is further required to elect a subspecies from among those autoimmune inflammatory disease recited in claim 5.

These species and subspecies are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each disease represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 3 is generic.

10. This application contains claims directed to the following patentably distinct species of the claimed Invention II: wherein the Th2-mediated disease is:

A) infectious diseases, or

B) an allergic disorder.

If Applicant elects Species A, Applicant is further required to elect a subspecies from among those infectious diseases recited in claim 19.

If Applicant elects Species B, Applicant is further required to elect a subspecies from among those allergic disorder recited in claim 20.

These species and subspecies are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each disease represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 17 is generic.

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
December 10, 2001

Phillip Gambel

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
12/11/01